



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2701]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Food Safety, Health, and Diet Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0345. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food Safety, Health, and Diet Survey

OMB Control Number 0910-0345--Reinstatement

This information collection supports the above captioned FDA survey. Under section 1003(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)), FDA is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation's food supply. Accordingly, we are proposing a survey to measure consumers' knowledge, attitudes, beliefs, and reported behavior about food safety and various topics related to health, nutrition, and physical activity. Survey questions covering hand washing, using food thermometers, cleaning cutting boards, and properly storing food support "Healthy People 2030" objectives relating to consumer food safety and help evaluate and develop strategies and programs to encourage consumers to adopt healthy lifestyles.

Since late 1990, we have deployed two separate surveys to address these topics: the "Food Safety Survey," approved under OMB control no. 0910-0345; and the "Health and Diet Survey," approved under OMB control no. 0910-0545. The surveys have provided data used in support of Nutritional Facts labeling and have helped inform the focus and scope of food safety educational campaigns. Because there are many related topic areas included in the two surveys, we have decided to combine them. The newly proposed "FDA Food Safety, Health, and Diet

Survey” will contain many of the same questions and topics as the previous surveys, measuring trends in food safety, diet knowledge, attitudes, and behaviors over time. The survey will focus on three major themes: *Eat*, *Shop*, and *Prepare*. These themes and survey questions were selected to gather information from consumers that will help FDA monitor and evaluate its programs and policies relating to menu labeling, use of the Nutrition Facts label, and food safety education activities.

The theme “Eat” will include questions related to eating at restaurants, including the frequency of eating at restaurants, awareness of menu labeling, and use of restaurant health inspection scores. It will also include questions about consumers’ overall dietary patterns, consumption of potentially risky foods, and perceptions of food safety risks. The theme “Shop” will include questions about use of the Nutrition Facts label, claims made on the front of food packages, and perceptions related to organic and genetically engineered foods. Finally, the theme “Prepare” will include questions about food handling practices related to cleaning hands and surfaces, separating raw meat from ready-to-eat foods, using food thermometers, preparing ready- and non-ready-to-eat foods, and properly chilling foods.

The survey will be administered using two sampling and administrative methodologies: a random-digit-dial telephone survey of both landline and cell phones, and an address-based, mail push-to-web survey. Previously, for both the “Health and Diet Survey” and the “Food Safety Survey,” only random digit dialing sampling techniques and telephone interviewing were used. By using both phone and address-based survey methods we will be able to explore the effects of survey mode and sampling frames on question responses with the goal of potentially transitioning the survey entirely to an address-based, mail push-to-web survey. A nationally representative sample of 2,000 adults will be selected at random to complete the telephone

survey. The addressed-based survey will seek 4,000 respondents. Additionally, methods will be employed to see if response bias is a problem in the survey. As noted above, participation in the survey will be voluntary. Cognitive interviews and a pretest will be conducted prior to fielding the survey.

In the *Federal Register* of July 3, 2017 (82 FR 30871), we published a 60-day notice requesting public comment on the proposed collection of information for OMB control no. 0910-0345, “Food Safety Survey.” Two comments were received. One discussed the importance of food safety, and the other comment was unrelated to the information collection.

In the *Federal Register* of July 18, 2017 (82 FR 32832), we published a 60-day notice requesting public comment on the proposed collection of information for OMB control no. 0910-0545, “Health and Diet Survey.” No comments were received. Because we are proposing to combine the surveys, we are consolidating the burden under OMB control no. 0910-0345 and discontinuing OMB control no. 0910-0545.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Cognitive interview screener (phone survey)	75	1	75	0.083 (5 minutes)	6
Cognitive interview screener (mail survey)	75	1	75	0.083 (5 minutes)	6
Cognitive interview (phone survey)	9	1	9	1	9
Cognitive interview (mail survey)	9	1	9	1	9
Pre-test screener (phone survey)	100	1	100	0.0167 (1 minute)	2
Pre-test screener (mail survey)	100	1	100	0.0167 (1 minute)	2
Pretest (phone survey)	40	1	40	0.25 (15 minutes)	10
Pretest (mail survey)	25	1	25	0.33 (20 minutes)	9
Survey screener (phone survey)	20,000	1	20,000	0.0167 (1 minute)	334

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Survey screener (mail survey)	40,000	1	40,000	0.0167 (1 minute)	668
Phone survey	2,000	1	2,000	0.25 (15 minutes)	500
Mail survey	4,000	1	4,000	0.33 (20 minutes)	1,320
Non-Response phone survey screener	200	1	200	0.0167 (1 minute)	3
Non-Response mail survey screener	200	1	200	0.0167 (1 minute)	3
Non-Response phone survey	100	1	100	0.167 (10 minutes)	16
Non-Response mail survey	100	1	100	0.167 (10 minutes)	16
Total					2,913

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

We will use a cognitive interview screener with 75 individuals for each of the phone and mail surveys to recruit prospective interview participants for a total of 150 individuals. We estimate that it will take a screener respondent approximately 5 minutes (0.08 hour) to complete the cognitive interview screener, for a total of 12 hours for both surveys. We will conduct cognitive interviews with 18 participants, 9 for each survey. We estimate that it will take a participant approximately 1 hour to complete the interview, for a total of 18 hours. Prior to the administration of the surveys, the Agency plans to conduct a pretest to identify and resolve potential survey administration problems.

We will use a pre-test screener with 175 individuals total; we estimate that it will take a respondent approximately 1 minute (0.0167 hour) to complete the pre-test screener, for a total of 4 hours. The pretest will be conducted with 65 total participants (40 phone and 25 mail); we estimate that it will take a participant 15 minutes (0.25 hour) to complete the phone pretest and 20 minutes (0.33 hour) for the mail pretest for a total of 19 hours.

We will use a survey screener to select an eligible adult respondent in each household to participate in the survey. A total of 60,000 individuals in the 50 states and the District of

Columbia will be screened by telephone or mail. We estimate that it will take a respondent 1 minute (0.0167 hour) to complete the screening, for a total of 1,002 hours for both phone and mail surveys. We estimate that 2,000 eligible adults will participate in the phone survey and 4,000 eligible adults will participate in the mail survey, the phone survey taking 15 minutes (0.25 hour) and the mail survey taking 20 minutes (0.33 hour), for a total of 1,820 hours.

We will use a non-response survey screener to select an eligible adult respondent in each household to participate in a non-response survey. A total of 400 participants in the 50 states and the District of Columbia will be screened by telephone or mail. We estimate that it will take a respondent 1 minute (0.0167 hour) to complete the screening, for a total of 6 hours for both the phone and mail surveys. We estimate that 200 respondents total, 100 for the phone survey and 100 for the mail survey, will complete the non-response survey taking 10 minutes (0.167 hour) for a total of 32 hours. Thus, the total estimated burden is 2,913 hours.

Dated: August 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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